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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/837,812	04/22/97	SAAVEDRA	61192

BRUCE M GAGALA  
LEYDIG VOIT AND MAYER  
TWO PRUDENTIAL PLAZA  
180 NORTH STETSON  
CHICAGO IL 60601-6780

SUITE 490

LEYDIG, VOIT & MAYER

EXAMINER	PAPER NUMBER
SKY	

DATE MAILED: 10/14/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

RECEIVED DOCKETING
DATE: 10-17-97
BY: RP
DUE DATE: 01-14-98

- ☒ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

- ☒ Claim(s) 1, 5 - 15, 19 - 27, 31 - 38 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1, 5 - 15, 19 - 27, 31 - 38 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Art Unit: 1502

Claims 1, 5-15, 19-27 and 31-38 are subject to restriction under U.S.C. 121 as being drawn to more than one distinct and independent invention.

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-26, drawn to polymers and polymer-containing compositions, classified in class 424, subclass 78.08.
- II. Claims 27-38, drawn to a nitric oxide administration method, classified in class 514, subclass 921.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as

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claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as for nitric oxide generation in a synthesis of an organic compound.

Because these inventions are distinct for the reasons given above and the search required for invention (II) is not required for (I) restriction for examination purposes as indicated is proper.

Claims 1, 5-15, 19-27 and 31-38 are generic to a plurality of disclosed patentably distinct species comprising polymeric backbones to which are attached X-N(O)NO groups. Claims 5-14 are limited to nitric oxide - releasing groups of various formulas. The Applicants must provisionally elect a single species of NO -

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releasing group such as one of the formulas of claims 5, 8, 10 and 1 or 12 with definite substituent groups also being chosen. Examples (I)-(V) of the instant specification are examples of nitric oxide compounds which are linked synthetically to polymer backbones and which can serve as the basis for election of a nitric oxide releasing group formula. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Claims 1, 5-15, 19-27 and 31-38 are generic to a plurality of disclosed patentably distinct species comprising polymeric compositions comprised of biopolymeric derivatives whose chemical structures vary substantially. Provisional election is mandatory of a single species of biopolymeric backbone listed in the claims, such as one of those of the Markush group of claim 1. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Claims 1, 5-15, 19-27 and 31-38 are rejected under judicially created policy as being comprised of improper Markush groups.

The claims define patentable distinct polymer derivatives whose properties are not predictable as being equivalent.

Claims 1, 5-15, 19-27 and 31-38 are rejected under 35 U.S.C. 112, paragraph 2.

The claims are unclear in chemical formula. They do not relate to the Applicants' disclosure since the polymer-nitric oxide releasing group formula of the claims is not a clear bond description of either polymer or linked NO groups. The claims define proposed or speculative structures and cannot be related to concrete polymeric materials.

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***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

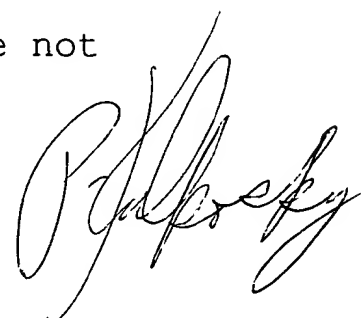
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-15, 19-27 and 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. Biochemistry 1990, 29 and 2802-2807.

The claims define compositions not distinguishable from the nitrogen oxide complexes of the reference. Thus, biopolymers are considered to be routine to attach or complex to the nitric oxide species, absent showing as to why backbone biopolymers are not routinely derivatizable in such a manner.

**Peter Kulkosky:cb**  
Primary Examiner

Friday, October 10, 1997



**PETER F. KULKOSKY**  
**PRIMARY EXAMINER**